



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,866	03/18/2004	Saeyoung Ahn	AP35740 - 072944.0181	6539
21003	7590	09/09/2005	EXAMINER	
BAKER & BOTTS 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			GEDEON, BRIAN T	
			ART UNIT	PAPER NUMBER
			3762	
DATE MAILED: 09/09/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No.	Applicant(s)	
	10/803,866	AHN ET AL.	
	Examiner	Art Unit	
	Brian T. Gedeon	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-13, 15 and 16 is/are rejected.
- 7) ☒ Claim(s) 3 and 14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7-14-2004</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter et al. (US Patent no. 6,853,863) in view of Li et al. (Bioelectromagnetics 18:2-7, 1997), and Howson et al. (US Patent no. 5,088,981).

In regards to claim 1, Carter et al. discloses an electrotherapy apparatus that can be embodied with the following: a storage medium, column 16 lines 57-63, to store programs for executing therapy; a micro controller 12 supervises the operation of the apparatus; an RMS to DC converter 212 and an analog-to-digital circuit 214, figure 10; and the ability to drive one or more channels and one or more electrodes, column 12 lines 9-15. Carter et al. does not disclose the electrode construction material. Li et al.

teaches that it is well-known in the art to electrochemically treat a tumor with a direct current stimulus using platinum coated electrodes, in which there is at least one of an anode and a cathode (see abstract).

The electrochemical therapy apparatus anticipated by Carter et al., Li et al. and Howson et al. should further be interpreted in view of Howson et al. Howson et al. discloses a device for the application of a therapeutic agent, in which the therapeutic agent is delivered via multiple channels, and each channel is independently controllable under fully automatic and unattended operation, column 4 lines 19-23 and 30-32. Therefore it would be obvious to one of ordinary skill in the art at the time the invention was made to combine the above references in order to better control the processes of the system.

In regards to claim 9, the device anticipated by Carter et al., Li et al. and Howson et al. describes the claimed device except the thickness of the platinum coating on the electrodes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to claim such ranges, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233

4. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carter et al. (US Patent no. 6,853,863) in view of Li et al. (Bioelectromagnetics 18:2-7, 1997) and Howson et al. (US Patent no. 5,088,981) as applied to claim 1, and further in view of Schroepel et al. (US Patent no. 6,738,663), Bonnet (US Patent no. 6,574,507) and Russell (US Patent no. 6,892,086).

In regards to claim 2, the device anticipated by Carter et al., Li et al. and Howson et al. describes the claimed device except the inclusion of an output driver. Schroepfel et al. discloses a device for the electrical treatment of cancer that includes: a DC amplifier within the signal processor 214, column 12 line 32; and a driver circuit 32 to regulate delivery of voltage and constant current to electrodes 215 and 216, column 11 lines 30-33. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the above references to control the driving voltage and constant current during electrochemical therapy.

Carter et al., Li et al. and Howson et al. describe the claimed device except the inclusion of a protection circuit. Russell discloses a medical electrode to prevent the passage of harmful current to a patient by means of a fuse 20, column 8 line 17-19. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the above references in order to decrease the probability that a patient could be harmed by excess current or electrical shock.

Carter et al., Li et al. and Howson et al. describe the claimed device except the inclusion of a detector. Bonnet discloses an electro-stimulation device with a voltage detector connected to the electrodes to detect a voltage in response to a current, column 12 lines 34-35 and 37-38. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the above references to allow the electrochemical therapy device to sense the applied voltage or current to the electrode unit and transmit it the converter.

5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carter et al. (US Patent no. 6,853,863) in view of Li et al. (Bioelectromagnetics 18:2-7, 1997) and Howson et al. (US Patent no. 5,088,981) as applied to claim 1 above, and further in view of Schroepel et al. (US Patent no. 6,738,663).

Carter et al., Li et al. and Howson et al. describe the claimed device except the warning signal unit. Shroepel et al. produces either an audible or vibratory warning signal 218 in order to alert the patient concerning low battery, open or short circuits and other conditions needing attention, column 12 lines 22-25. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the above references in order to signal a technologist or patient when there is a potential problem with the device.

6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carter et al. (US Patent no. 6,853,863) in view of Li et al. (Bioelectromagnetics 18:2-7, 1997) and Howson et al. (US Patent no. 5,088,981) as applied to claim 2 above, and further in view of Russell (US Patent no. 6,892,086) and Sluijter et al. (US Patent no. 6,161,048).

Carter et al., Li et al. and Howson et al. describe the claimed device except the inclusion a protection circuit. Russell discloses a medical electrode to prevent the passage of harmful current to a patient by means of a fuse 20, column 8 line 17-19. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the above reference in order to cutoff the power in the event that current or voltage falls outside of the accepted range.

Carter et al., Li et al. and Howson et al. describe the claimed device except the acceptable ranges of voltage and current for the power cutoff circuit. It would have been obvious to one having ordinary skill in the art at the time the invention was made to claim such ranges, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carter et al. (US Patent no. 6,853,863) in view of Li et al. (Bioelectromagnetics 18:2-7, 1997) and as applied to claim 2 above, and further in view of Russell (US Patent no. 6,892,086) and Tu (US Patent no. 6,235,024).

Carter et al., Li et al. and Howson et al. describe the claimed device except that the power is cutoff after measured resistance value exceeds a predetermined value. Russell discloses the power protection circuit by means of a fuse 20. Tu discloses a catheter system having ablation capability, in which the power to the ablation element 13 is cutoff when a measured impedance value exceeds an accepted value, column 5 lines 57-60. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the above references in order to protect the device by cutting the power if the measured resistance goes out of accepted limits.

8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carter et al. (US Patent no. 6,853,863) in view of Li et al. (Bioelectromagnetics 18:2-7, 1997) and Howson et al. (US Patent no. 5,088,981) as applied to claim 1 above, and further in view of Tanouye et al. (US Patent no. 6,521,462).

Carter et al., Li et al. and Howson et al. describe the claimed invention except the does not state that the electrodes can be made of tungsten. Tanouye et al. discloses a device for detecting seizures and uses tungsten electrodes, column 7 line 46. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to select a medical electrode made of tungsten with greater adhesive properties to enhance the placement of electrodes.

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carter et al. (US Patent no. 6,853,863) in view of Li et al. (Bioelectromagnetics 18:2-7, 1997) and Howson et al. (US Patent no. 5,088,981) as applied to claim 1 above, and further in view of Hwang et al (US Patent no. 6,919,168).

In regards to claim 8, Carter et al., Li et al. and Howson et al. describes the claimed device except does not state that the electrodes are platinum coating is achieved by magnetron sputtering. Hwang et al. teaches that an electrode layer 16 such as platinum, column 24 lines 57-58, can disposed onto a substrate magnetron sputtering, column 25 lines 5-7. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the magnetron sputtering method to apply a coating to platinum to the electrode.

10. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carter et al. (US Patent no. 6,853,863) in view of Li et al. (Bioelectromagnetics 18:2-7, 1997) and Howson et al. (US Patent no. 5,088,981) as applied to claim 1, and further in view of Schaefer et al. (US Patent no. 6,638,277).

Carter et al., Li et al. and Howson et al. describe the claimed invention except the distributor connecting the electrode unit. Schaefer et al. shows a distributor 48 that connects a plurality of independent electrodes terminal elements 54, to a signal generator 50, column 6 lines 40-49. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the electrodes to use a distributor to distribute electrical power to the electrodes.

11. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carter et al. (US Patent no. 6,853,863) in view of Li et al. (Bioelectromagnetics 18:2-7, 1997) and Howson et al. (US Patent no. 5,088,981) as applied to claim 1, and further in view of Sluijter et al. (US Patent no. 6,161,048).

In regards to claim 11, Carter et al., Li et al. and Howson et al. describe the claimed invention except does not show the connectors for the electrodes. Sluijter et al. shows a connector 10 to electronically connect the hub portion 3 to the electrode shaft 2 and power supply units 4 and 5, column 4 lines 38-43. The examiner interprets the described embodiments of the connectors as equivalents and functionally recognized in the art, and specification of the type of connector would constitute design choice.

Therefore it would be obvious to one of ordinary skill in the art at the time the invention was made to combine the above references to provide a means of connection between the electrodes and power supply.

12. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carter et al. (US Patent no. 6,853,863) in view of Li et al. (Bioelectromagnetics 18:2-7, 1997) and

Howson et al. (US Patent no. 5,088,981) as applied to claim 10 above, and further in view of Desai (US Patent no 5,861,002).

Carter et al., Li et al., and Howson et al. describe the claimed invention except the guide cap that surrounds the distributor connecting area of the electrode. Desai discloses an endoscopic surgical instrument, which has a retractable electrode assembly 20, which includes sheath 238 for guiding the angular orientation of the electrode. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the above references to better guide the electrode to the tissue requiring treatment.

13. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carter et al. (US Patent no. 6,853,863) in view of Li et al. (Bioelectromagnetics 18:2-7, 1997) and Howson et al. (US Patent no. 5,088,981) as applied to claim 12 above, and further in view of Hill et al. (US Patent no. 6,765,471).

Carter et al., Li et al. and Howson et al. describe the claimed invention except the flexible tube with the plurality of wires surrounding the outer circumference of the tube. Hill et al. shows an endotracheal/esophageal stimulation system having an embodiment that may comprise of a tube 103, column 11 lines 36-37, which may be flexible, column 11 line 54, and has an array of wire electrodes 16 wrapped around the outer surface of the tube, column 12 lines 17-19. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the above references to moveably insert therapeutic device into the body.

Art Unit: 3762

14. Claims 15 and 16 rejected under 35 U.S.C. 103(a) as being unpatentable over Carter et al. (US Patent no. 6,853,863) in view of Li et al. (Bioelectromagnetics 18:2-7, 1997) and Howson et al. (US Patent no. 5,088,981).

In regards to claim 15, Carter et al., Li et al. and Howson et al. describe the claimed invention except the wave-shape of the electrodes. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a wave-shaped electrode since it was well known in the art the time the invention was made that a wave-shaped electrode increases overall surface area contact with living tissue to achieve maximum therapeutic benefits.

In regards to claim 16, Carter et al., Li et al. and Howson et al. describe the claimed invention except the coil-shape of the electrodes. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a coil-shaped electrode since it was well known in the art the time the invention was made that a coil-shaped electrode increases overall surface area contact with living tissue to achieve maximum therapeutic benefits.

Allowable Subject Matter

15. Claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

16. Claim 14 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Herbst et al (US Patent no. 6,021,347) discloses a device for electrochemical treatment of malignant tumors. Johnson et al. (US Patent no. 6,826,429) discloses a device for the interferential current treatment apparatus. Whitehurst et al. (US Patent no. 6,901,296) describes methods and systems for direct electrical current stimulation as a therapy for cancer and other neoplastic disease.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (703) 272 3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (703) 272 6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert E Pezzuto
Supervisory Patent Examiner
Art Unit 3762

BTG